DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 26, 2015

Rogers Sciences Incorporated
% Mr. Raymond Kelly
Licensale Incorporated
1801 Wedemeyer Street
San Francisco, California 94129

Re: K140386
Trade Name: Lumina 24
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulatory Class: Class II
Product Code: GEX
Dated: May 14, 2015
Received: May 18, 2015

Dear Mr. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140386

Device Name
Rogers Sciences Inc (RSI) Lumina 24

Indications for Use *(Describe)*
Intended to provide light to the body. Generally indicated to dermatology use for the treatment of benign superficial and pigmented lesions in patients with Fitzpatrick Skin Types II and III excluding vascular lesions such as hemangiomas, telangiectasia, and benign pigmented lesions such as solar lentigo, age spots, or freckles.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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ROGERS SCIENCES, INC.
Address: 79 Golf Street, Southbridge, MA 01550 USA **Phone:** 888-691-2321 **Web:** www.rogersscienceinc.com

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.(c)

Date Prepared: May 26, 2015

Applicant
Rogers Science Inc.
79 Golf Street,
Southbridge, MA 01550 USA
Phone: 617-435-5152
Web: www.rogersscienceinc.com

Contact Person
Raymond Kelly
Licensale Inc.
57 Lazy Brook Rd
Monroe, CT 06468 USA
Phone: (203) 880-4091

Device Information

Trade/Proprietary Name:	Lumina 24
Common Name:	Powered Laser Surgical Instrument
Classification Name:	Laser Surgical Instrument
Regulation Medical Specialty:	General & Plastic Surgery
Review Panel:	General & Plastic Surgery
Product Code:	GEX
Device Class:	2
Regulation Number:	878.4810

Predicate Device Information
K082247 “Evis MD Platinum Red Light Therapy” cleared by FDA on October 10, 2008

Indications for Use
Intended to provide light to the body. Generally indicated to dermatology use for the treatment of benign superficial and pigmented lesions in patients with Fitzpatrick Skin Types II and III excluding vascular lesions such as hemangiomas, telangiectasia, and benign pigmented lesions such as solar lentigo, age spots, or freckles.

Device Description

The Rogers Sciences Inc.'s Lumina 24 is a light-emitting diode therapy system used to treat superficial and pigmented skin lesions. It consists of a battery-powered light source (Illuminator), optical fibers, and an optical pad (Light Patch). The Light Patch and its adhesive are made from hypoallergenic materials designed to be safe for Fitzpatrick Skin Types II and III.

The Lumina 24 system applies Red Light (RL) therapy directly to the treatment area of the skin. To begin treatment, the patient applies the Light Patch to the treatment area and turns on the Illuminator. Light travels from the Illuminator through the optical connector to the Light Patch and to the skin. The Illuminator turns off automatically after 1 hour but treatment may be stopped at any time by turning it off manually. Because Lumina 24 is portable and battery-powered, treatment can take place while the patient is doing other activities.

Substantial Equivalence

Equivalence was determined using a side by side tabular comparison between the predicate and proposed devices which included: Features, Intended Use, Labeling, Materials, Specifications, Performance Data, and Technological Aspects.

Basic Unit Characteristics	**Lumina 24**	**K082247 EVIS MD Platinum Red Light Therapy**
Indications	Intended to provide light to the body. Generally indicated to dermatology use for the treatment of superficial and pigmented lesions in patients with Fitzpatrick Skin Types II and III excluding vascular lesions such as hemangiomas, telangiectasia, or other benign pigmented lesions such as solar lentigo, age spots, or freckles.	Intended to provide light to the body. Generally indicated to dermatology use for the treatment of superficial, benign vascular and pigmented lesions "such as but not limited to solar lentigines, sun spots, liver spots and age spots.
Power (mW)	0.417 ± 20%	80.00
Increments of Power Available (mW)	0.417 ± 20% 0.834 ± 20%	80.00
Irradiance (mW/cm^2)	0.580 ± 20%	80.00
Fluence (J/cm^2)	2.088	192.00
Duration (min)	60	20
Beam Diameter (mm)	7.5	7.5
Pulse Rate (Hz)	Continuous	Continuous
Pulse Duration (ms)	0	0
Spot Size at Target (cm^2)	79	79
Wavelength (nm)	630 ±5	630 ±5
Beam Mode	LED, 42 mil square	LED, 42 mil square
Beam Divergence Angle (Deg.)	0.5" aperature (Theta = 30)	0.5" aperature (Theta = 30)
Aiming Beam Type (Wavelength)	630 ±5	630 ±5
Controls (Power, Readouts)	Display, control buttons	Display, control buttons
Laser Medium	Light Emitting Diode	Light Emitting Diode

Basic Unit Characteristics	**Lumina 24**	**K082247 EVIS MD Platinum Red Light Therapy**
Energy Source	Red Light	Red Light
Cooling Method	Air	Air
Display (Control Panel, Printouts)	display; control buttons	display; control buttons
Power Calibration	NA	NA
Clean/Disinfect	Wipe with alcohol between use	Wipe with alcohol between use
Software	None	None
Timer	Begins counting at the time the Power Switch is tuned On and the Light Patch establishes contact with the Illumination Device. After 1-hour the power is turned off	Begins counting at the time tuned on; 20 Minutes per target area, 2 treatments per week. Audible beep every 3 minutes for 20 minutes, Timer to turn off the power after 1-hour
Treatment Length	4 weeks first phase, maintenance long term	4-8 weeks first phase, maintenance long term
Treatment Area	Torso below neck	Torso below neck
Handpiece Shape	Rectangular shaped	Rectangular shaped
Handpiece Material	Biocompatible polymer with adhesive strip	Biocompatible polymer with adhesive strip
Handpiece Thickness	≤ 8 mm	≤ 8 mm
Handpiece Weight	≤ 50 grams	≤ 50 grams
Voltage Current	Set by potentiometer	Set by potentiometer
On-Off Button	External On/Off push-button	External On/Off push-button
Power Safeguard	If current from the battery increases beyond a threshold, the Power Safeguard shuts off power	If current from the battery increases beyond a threshold, the Power Safeguard shuts off power
Status Indicator Conditions	On-Off status, self-test, failures, disconnect during treatment, fault condition, therapy completion	On-Off status, self-test, failures, disconnect during treatment, fault condition, therapy completion
Therapy Thermal cut-out	When the LED approaches 50ºC junction temperature, the internal thermistor allows system to shut off	When the LED approaches 50ºC junction temperature, the internal thermistor allows system to shut off
Surface Temperature	Surface temperature ≤ 43ºC and meets IEC 60601-1	Surface temperature ≤ 43ºC and meets IEC 60601-1
Surface Temperature Dissipation	Temperature does not exceed 43ºC	Temperature does not exceed 43ºC
Positioning On Subject	Able to be placed on the target location by the user	Able to be placed on the target location by the user
Storage conditions	10-27°C and 40-60%RH	10-27°C and 40-60%RH
Electrical Safety	Compliant to safety requirements for electrical equipment IEC60601-1	Compliant to safety requirements for electrical equipment IEC60601-1
Cabling/Coupling Electrical Safety	Compliant to requirements for patient-applied parts with a Type BF rating. This is the requirement for electrical isolation in terms of high-potential dielectric withstand and current leakage	Compliant to requirements for patient-applied parts with a Type BF rating. This is the requirement for electrical isolation in terms of high-potential dielectric withstand and current leakage
Shelf Life	12 months shelf and 12 months Useful Life	12 months shelf and 12 months Useful Life

Clinical Summary:

Study Objective

This study compared the Light Emitting Diode therapy of the Lumina 24™ system and the EVIS MD Platinum system. Both of these systems use Red Light (630nm) technology. Both of these systems were compared for the treatment of superficial and pigmented lesions in patients with Fitzpatrick Skin Types II and III excluding vascular lesions such as hemangiomas, telangiectasia, or other benign pigmented lesions such as solar lentigo, age spots, or feckles.

Primary Endpoint

- Evaluated % clearance of lesions based on a quartile scale (ex. Q1: >75%). Clearance was determined by the exact number of lesions counted at an anatomical site before (pre) or after (post) treatment with one of the study devices (Lumina24 or EVIS MD). Post-treatment evaluation occurred one-month after completing treatment. Evaluation was performed by a panel of four independent dermatology providers who were blinded as to treatment used and whether the site was pre or post-intervention. The evaluators based the lesion counts on high-resolution digital images taken by the Principal Investigator.

  The percent clearance was calculated by the following formula:

  ((BT – PT) / BT) x 100 = percent reduction in lesions, where

  BT = before treatment lesion number in the anatomic area treated
  PT = post treatment lesion number in the anatomic area treated

  The subjects were then grouped into four Quartiles, where:

  Q1 = greater than 75% clearance of lesions
  Q2 = 50% - 75% clearance of lesions
  Q3 = 25% -50% clearance of lesions
  Q4 = less than 25% clearance of lesions

Secondary Endpoints

- Mean score on subject satisfaction with skin appearance scale at 1 week, 2 weeks, 3 weeks and at 1 month follow-up visit using the 100mm Visual-Analog-Scale (VAS), with 0 being very dissatisfied and 10 being very satisfied.

- Self-reported adverse events as documented on subject log

- Evaluate safety of the Lumina 24™ Light Patch (LP). Rogers Sciences (manufacturer of the Lumina 24™ system) measured pre- and post- uniformity and repeatability of each LP used in the study. ‘Uniform’ is specified as irradiance at each measurement point within +/-20% of the mean irradiance value. 'Repeatable’ is specified as irradiance at each measurement point within +/-20% of the median over 3 distinct measurements. Measurements to be taken with a calibrated photometer.

Study Methodology

This was a prospective, randomized, controlled, masked study. Subjects meeting all inclusion/exclusion criteria and consenting to participation were enrolled and given both the Lumina 24™ system and the EVIS MD Platinum for use at home to be applied to designated treatment areas chosen by the study clinician. The clinician picked a treatment location on the arms, legs, back, chest, and/or torso. The clinician selected a part of the body which had damaged skin on an area that is equal on both sides (symmetrical) of the body. Only one treatment area, for each side of the body was identified by the clinician for treatment. Randomization using standard randomization number table determined which device was used on the right and left side of the body. The treatment locations and how to apply a device to a given location were described and shown by the Principal Investigator to the subject. The subject used each device twice a week; both devices were applied on a Monday and Wednesday. Each device was applied on the same day but at separate times (the devices were not be applied and used simultaneously on a given treatment day). The Lumina 24™ system was applied for a 1-hr time period and the EVIS MD Platinum was applied for 18 minutes. Self-assessments were documented weekly (weeks 1, 2, and 3) and at 1 month (30 days +/- 7 days) for satisfaction with skin appearance. Adverse events were self-assessed as applicable. Photographs of each treatment site for each device were taken pre- and post- treatment.

STUDY RESULTS

A total of 17 subjects completed the study. Of the 17 subjects, four (4) had lesions on both sides of their legs. Two (2) of these subjects had lesions on the lower leg, and the other two (2) subjects had lesions on the upper leg. Five (5) subjects had lesions on both sides of their upper chest. The remaining eight (8) subjects had lesions on both sides of their arms/biceps.

Eight (8) subjects had a Fitzpatrick Skin Type of 2 and the remaining nine (9) subjects had a Fitzpatrick Skin Type of 3.

Patient Number	Anatomical Location	Fitzpatrick Skin Type	Side of Body EVIS Applied	Side of Body Lumina24 Applied
1	Upper Leg	2	Left	Right
2	Chest	3	Right	Left
3	Chest	3	Right	Left
4	Upper Leg	3	Right	Left
5	Lower Leg	2	Left	Right
6	Lower Leg	3	Left	Right
7	Chest	2	Left	Right
8	Chest	2	Left	Right
9	Arm	2	Left	Right
10	Chest	3	Right	Left
11	Arm	2	Left	Right
12	Arm	2	Left	Right
13	Arm	3	Left	Right
14	Arm	3	Right	Left
16	Arm	3	Left	Right
17	Arm	2	Left	Right
19	Arm	3	Right	Left

Patient Response

On a weekly basis subjects filled out a study log for both the Lumina24 and EVIS MD Platinum system. As part of the log, each subject marked their satisfaction with their skin appearance after treatment at 1 week, 2 weeks, 3 weeks, and at 1-month follow up visit using the 100mm VAS. The week to week response variation per subject was not significant for both the Lumina24 and EVIS MD Platinum systems. The variation in satisfaction across all subjects for all weeks was not significant. The variation in satisfaction between devices for all weeks and all subjects was not significant.

No Adverse Events were reported by any subjects during their treatments with either the Lumina24 or EVIS MD Platinum system devices.

	Mean VAS (10 pt Scale) for All Subjects (Based on Device)				
	Week 1	Week 2	Week 3	Week 4	Weekly Avg.
Lumina24	3.9000	4.6857	5.2500	5.7429	4.8946
EVIS	4.2964	4.7250	5.4214	5.9214	5.0911

BEFORE				AFTER			
	Lumina24 Illumination Device	Light Patch	EVIS Device		Lumina24 Illumination Device	Light Patch	EVIS Device
Subject	mW/cm2	mW/cm2	mW/cm2	Subject	mW/cm2	mW/cm2	mW/cm2
1	1.15	0.5946	12.15	1	1.16	0.5947	12.22
2	1.19	0.5524	10.85	2	1.19	0.5434	10.82
3	1.22	0.5532	11.02	3	1.22	0.5424	11.00
4	1.14	0.5501	10.99	4	1.12	0.5650	10.94
5	1.16	0.5843	11.03	5	1.15	0.5796	11.01
6	1.15	0.5409	12.09	6	1.15	0.5374	12.11
7	1.15	0.6119	12.08	7	1.16	0.6087	12.10
8	1.18	0.5459	10.87	8	1.18	0.5452	10.88
9	1.19	0.5932	12.14	9	1.20	0.5914	12.13
10	1.19	0.5281	10.85	10	1.18	0.5263	10.85
11	1.23	0.5329	11.00	11	1.23	0.5333	11.01
12	1.21	0.6020	11.01	12	1.20	0.6018	11.00
13	1.15	0.5949	10.85	13	1.17	0.5902	10.84
14	1.16	0.5688	12.07	14	1.17	0.5671	12.07
16	1.16	0.5737	12.05	16	1.17	0.5741	12.06
17	1.14	0.5767	11.07	17	1.15	0.5707	11.08
19	1.18	0.5683	10.85	19	1.17	0.5677	10.89

Before and after test measurements of the Study Devices. Measurements are of irradiance (mW/cm^2).

Lumina24 Device Testing

Device testing on the light output of the Lumina24 Illumination Device and Light Patches (LP) as well as on the EVIS MD Platinum System were undertaken before and after subjects used the devices during their study treatment. For the LPs, each one was measured before and after treatment for uniformity and repeatability.

There was little change in irradiance output across the devices from before and after the study took place for a given subject. The repeatability of these devices shows that there was less than a 3% difference in light output before and after the study for each subject.

The uniformity on a given LP and across all the LPs given to subject was less than 10% before and after the study. The uniformity between the devices before and after the study for each subject was less than +/-20%.

The Lumina24 system for each subject held up to the specifications of uniformity and repeatability outlined as secondary endpoints of the clinical study.

AVERAGE UNIFORMITY

	Lumina24 Light Patch Before	Light Patch After	Difference Before and After
Subject	mW/cm2	mW/cm2	mW/cm2
1	-2.51%	-2.53%	-0.23%
2	4.75%	6.30%	-1.83%
3	4.62%	6.48%	-1.78%
4	5.15%	2.59%	2.40%
5	-0.75%	0.08%	-0.92%
6	6.74%	7.34%	-0.68%
7	-5.50%	-4.94%	-0.45%
8	5.88%	6.00%	-0.08%
9	-2.28%	-1.97%	-0.26%
10	8.95%	9.25%	-0.32%
11	8.12%	8.05%	0.10%
12	-3.79%	-3.75%	-0.02%
13	-2.57%	-1.76%	-0.79%
14	1.93%	2.22%	-0.29%
16	1.09%	1.02%	0.09%
17	0.57%	1.61%	-1.00%
19	2.01%	2.13%	-0.12%

Uniformity test measurements of the Study Devices. Measurements are of irradiance (mW/cm^2) difference from before and after the study on a given device used by a subject.

REPEATABILITY DIFFERENCE

	Lumina24 Illumination Device	Light Patch	EVIS Device
Subject	mW/cm2	mW/cm2	mW/cm2
1	0.86%	0.02%	0.57%
2	0.00%	-1.66%	-0.28%
3	0.00%	-1.99%	-0.18%
4	-1.79%	2.64%	-0.46%
5	-0.87%	-0.82%	-0.18%
6	0.00%	-0.64%	0.17%
7	0.86%	-0.53%	0.17%
8	0.00%	-0.12%	0.09%
9	0.83%	-0.30%	-0.08%
10	-0.85%	-0.34%	0.00%
11	0.00%	0.08%	0.09%
12	-0.83%	-0.04%	-0.09%
13	1.71%	-0.79%	-0.09%
14	0.85%	-0.29%	0.00%
16	0.85%	0.08%	0.08%
17	0.87%	-1.05%	0.09%
19	-0.85%	-0.12%	0.37%

Repeatability test measurements of the Study Devices. Measurements are of irradiance (mW/cm^2) difference from before and after the study on a given device used by a subject.

Percent Clearance

Within 30 days of last subject completing 1 month visit, a panel of 4 experts, in a blinded manner, reviewed the 1 month visit photos of the treated sites from all enrolled subjects and evaluated the number of lesions for a given anatomical site before (pre) or after (post) treatment using one of the treatment devices. The following are the quartile scale of percent lesions clearance before and after treatment with the Lumina24 and EVIS MD Platinum systems.

	ALL PATIENTS	N=17
	Quartile Clearance Lumina24	Quartile Clearance EVIS
Q1: 76-100%	1	1
Q2: 51-75%	0	1
Q3: 26-50%	6	5
Q4: 0-25%	10	10

Percent lesions clearance based on quartile scale for each device across all patients (N=17).

The 2 x 4 matrix was evaluated for statistical significance by a Chi Square analysis of the Quartile results with the following outcome:

- Chi Square of the Quartile analysis: p=0.78
- Study has >80% probability detecting a 15% or greater difference in lesion clearance between Lumina and Evis at p=0.05
- Conclusion: Devices are substantially equivalent in clearance of lesions related to photo aging.

Conclusion

Based on the results of the 4-member review panel of the pre- and post- images of the 17 subjects who were treated with the Lumina24 system and the EVIS Platinum MD system, there was no statistically significant difference between the two devices. Significant difference being defined as an 80% confidence that there is less than 20% difference between the Lumina24 system and the EVIS Platinum MD system. Furthermore none of the 17 subjects enrolled had an AE (Evis AE =0, Lumina24=0).

Due to the lack of difference in clinical response to the two devices as determined by an independent and qualified review panel, RSI has determined and demonstrated that the Lumina24 system and the EVIS MD Platinum system are clinically Substantially Equivalent (SE).